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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/065,672 04/23/98 BILLING-MEDEL P 6086

023492
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DEPT. 377 - AP6D-2
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HM12/1201

EXAMINER

TURNER, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

12/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/065,672

Applicant(s)

Billing-Medel

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1647



☒ Responsive to communication(s) filed on 8-29-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-6, 11, 12, 15, and 18-21 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6, 11, 12, 15, and 18-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Response to Amendment

1. The Examiner of U.S. Patent application SN 09/065,672 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1647.
2. The substitute declaration filed 6-19-00 has been entered into the record.
3. The amendment filed 8-29-00 has been entered into the record and has been fully considered.
4. Claims 1-6, 11-12, 15 and 18-21 are pending.
5. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Rejections

Double Patenting

6. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-6, 11-12, 15 and 18-21 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-16, 30, 33, 35, 38 and 48 of copending Application No. 09/065,383. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fragment and percent identity language in instant claims renders the claimed nucleotides obvious in view of the claims of the '383 application because the nucleotide fragments with % identity of instant claims are encompassed by the claims of the '383 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants argue that deletion of "fragment" language from the claims obviates the rejection.

Applicant's arguments filed 8-29-00 have been fully considered but they are not persuasive because "complements thereof" encompass partial complements, i.e., fragments.

Claim Rejections - 35 USC § 101 and 112

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-6, 11-12, 15 and 18-21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility.

The specification contemplates the use of the disclosed nucleic acids for the identification of markers as indicative of a prostate tissue disease or condition, see in particular p. 11, lines 16-17. The specification further discloses that the isolated nucleic acids of the invention are specific to a PS128 polynucleotide and that the nucleic acids may be used to detect the PS128 sequence in a test sample, see in particular p. 4, lines 10-11. Yet the specification discloses that PS128 is expressed in tissues other than prostate and in normal prostate as well as in prostate cancer tissue, see in particular Figures 3-4. In addition, the claims recite homologous sequences which may not specifically detect the designated PS128 sequence, but alternatively would detect related sequences. Thus the designated utility does not appear to be either specific and substantial or credible because the sequences appear to detect sequences from tissues other than prostate and for prostate regardless of disease or condition. Thus, the use for the nucleic acids appears to merely rely on the inherent properties of any nucleic acid to hybridize to complementary sequences. Therefore, the disclosed nucleic acids merely constitute research reagents for further experimentation to discover a "real-world" use. The examiner further notes that the specification fails to disclose a PS128 gene, open reading frame, polypeptide or epitope for which the nucleic

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acid fragments appear to be specific. For these reasons there does not appear to be either a specific and substantial, credible asserted utility or a well-established utility for the claimed nucleic acids.

11. Claims 1-6, 11-12, 15 and 18-21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

12. Claim 1-6, 11-12, 15 and 18-21 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicants submit the Wisconsin Sequence Analysis Program as supported by the specification on page 12, beginning at line 10, argue an article by M. H. Van Regenmortel which was not provided to the examiner, are well known and described in the scientific, commercial and patent literature for methods of identifying epitopes in a novel peptide sequence and point further to a web site and a patent application PCT/US97/00485 for further description of how to identify epitopes.

Applicant's arguments filed 8-29-00 have been fully considered but they are not persuasive. In regards to the cited references applicants imply that the references including the

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Wisconsin Sequence Analysis Program, the web site and the PCT/US97/00485 application provide enabling written description support to determine the nucleic acid sequences, epitopes and open reading frames recited in the claims. Contrarily such arguments highlight the specifications deficiency in providing a written description support at the time of filing for that which constitutes the nucleic acid sequences of the invention which share 90% identity, constitute at least one epitope and designate an open reading frame. The examiner notes that the specification at p. 12 beginning at line 10 merely states that "databanks can be used as a method to determine the uniqueness of a designated sequence." Such description fails to teach the claimed nucleic acids which require written description support. In regards to methods for determining epitopes, the examiner notes that the specification fails to specify an open reading frame for the claimed nucleic acids, a polypeptide produced thereby or any epitope formed by such encoding sequences. Thus, the specification lacks written description support of the claimed invention.

13. Claims 1-6, 11-12, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have amended the claims to recite nucleic acid sequences selected from the group consisting of position 4-269 of SEQ ID NO:2, positions 1-276 of SEQ ID NO:4 and positions 1-276 of SEQ ID NO:5. Such recitations have been added without identification of

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support in the specification as originally filed and no support for such recitations has ^{been} ~~bee~~ found by the examiner. Thus, such recitations constitute new matter.

Priority

14. Applicants claim to priority under 35 USC 120 to patent application 08/838,968 is denied because applicant does not have support for 100% identity of SEQ ID Nos:1-5 and 12-14, see Figure 1. Thus the priority date awarded instant claims is the instant filing date, 4-23-98.

Applicants clarification of the discrepancies in sequence indicate that the invention was not perfected at the time of filing the provisional application. As a claim may only have a single priority date, the date of invention as directed to the recited SEQ ID NO's is the date of instant filing, 4-23-98. As the recited subject matter of the amended claims is also not supported by the priority application and constitutes new matter, the earliest possible date of invention is instant filing absent evidence of support.

Claim Rejections - 35 USC § 102 or 103

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-3, 15 and 18-21 are rejected under 35 U.S.C. 102(a) as being anticipated by any one of the following references alone; Genbank Accession No. AA631976, 31 October 1997, and Genbank Accession No. AA578209, 11 September 1997.

Applicants argue that as “fragment” language has been deleted and the percent identity is raised in general that the amendment obviates the rejection.

Applicant's arguments filed 8-29-00 have been fully considered but they are not persuasive because “complements thereof” encompass partial complements, i.e., fragments and SEQ ID NO:2 is taught with 100% identity.

18. Claims 1-3, 15 and 18-21 stand rejected under 35 U.S.C. 102(b) as being anticipated by any one of the following references alone; Genbank Accession No. Z39296, 27 October 1994, Genbank Accession No. R94063, 1 September 1995, Genbank Accession No. H72049, 2

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November 1995, Genbank Accession No. H83957, 16 November 1995 and Genbank Accession No. T83743, 1 April 1995.

Applicants argue that as “fragment” language has been deleted and the percent identity is raised in general that the amendment obviates the rejection.

Applicant's arguments filed 8-29-00 have been fully considered but they are not persuasive because “complements thereof” encompass partial complements, i.e., fragments and SEQ ID NO:2 is taught with 100% identity.

19. Claims 1-6, 11-12, 15 and 18-21 stand directed to an invention not patentably distinct from claims 10-16, 30, 33, 35, and 38-48 of commonly assigned 09/065,383. Specifically, instant claims drawn to polynucleotide fragments and fragments with a percent identity are encompassed by claims 10-16, 30, 33, 35 and 38-48 because the subject nucleotides are shared in common. Thus, the nucleotides of instant claims are rendered obvious by the claims of the ‘383 application. .

Commonly assigned ‘383, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78© and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to

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name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f). Claims 1-6, 11-12, 15 and 18 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/065,383 which has a common inventor and is currently commonly owned with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application. Instant claims drawn to polynucleotide fragments and fragments with a percent identity are encompassed by claims 10-16, 30, 33, 35 and 38-48 because the subject nucleotides are shared in common. Thus, the nucleotides of instant claims are rendered obvious by the claims of the '383 application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

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Applicants wish the examiner to hold this rejection in abeyance pending determination of allowability.

Applicant's arguments filed 8-29-00 have been fully considered but they are not persuasive because there is no provision for holding the rejection in abeyance and further no claims have been allowed.

20. Claims 1-6, 11-12, 15 and 18-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the following references; Genbank Accession No. AA631976, 31 October 1997, and Genbank Accession No. AA578209, 11 September 1997, Genbank Accession No. Z39296, 27 October 1994, Genbank Accession No. R94063, 1 September 1995, Genbank Accession No. H72049, 2 November 1995, Genbank Accession No. H83957, 16 November 1995 and Genbank Accession No. T83743, 1 April 1995, as set forth above, Genbank Accession No. N74923, 5 April 1996, Genbank Accession No. AA280704, 3 March 1997, Genbank Accession No. Z39296, 27 October 1994, and Genbank Accession No. N80180 4 April 1996 in view of Sambrook et al, Molecular Cloning, 1989, 16.1-16.16.

Applicants argue that as “fragment” language has been deleted and the percent identity is raised in general that the amendment obviates the rejection.

Applicant's arguments filed 8-29-00 have been fully considered but they are not persuasive because “complements thereof” encompass partial complements, i.e., fragments and SEQ ID NO:2 is taught with 100% identity.

Status of Claims

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21. No claims are allowed.

Conclusion

22. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
November 29, 2000

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud